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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,416	03/06/2002	Gerald Cagle	1733 US FA	1351

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,416	CAGLE ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted February 17, 2004 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added claims lack support from the specification, or the claims, as originally filed. Particularly, following characteristics recited in the newly added claims are not properly described in the specification or the claims as original filed: a) "in a concentration effective for treatment and/or prophylaxis of a gram-positive bacterial infection of at least one tissue of the eye," b) 'at least one ophthalmically acceptable excipient that reduces a rate of removal of the composition from the eye." There is no proper written description in the specification to support such limitations.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Cochran et al. (US 6,337,329, IDS AA4).

3. Cochran et al. teaches an ophthalmologic composition comprising an oxazolidinone, such as linezolid, and a method of using the same for treating eye infection. The composition may be in the form of solution, cream, ointment, emulsion, suspension and slow released form. See, particularly, examples 6 and 7 in col. 6, and the claims. Note the slow released form would inherently comprising excipient that reduces a rate of removal of the composition from the eye. Further, the forms of cream, or ointment, would inherently comprise excipients that would qualify as thickener, and those thickeners would that reduces a rate of removal of the composition from the eye.

Claim Rejections 35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. (US 6,337,329, IDS AA4). In view of Cagle (WO 90/01933, IDS).

Cochran et al. teaches an ophthalmologic composition against bacterial infection, including gram-positive bacterial, comprising an oxazolidinone, such as linezolid, and a method of using the same for treating eye infection. The composition may be in the form of solution, cream, ointment, emulsion, suspension and slow released form. See, particularly, column 2, lines 36-67, examples 6 and 7 in col. 6, and the claims.

Cochran et al. does not teach expressly adding at least one ophthalmically acceptable excipient that reduces a rate of removal of the composition from the eye, or viscosity enhancing agent.

However, Cagel teaches that, for a ophthalmic composition, viscosity increase above that of simple aqueous solutions may be desirable to increase ocular absorption of the active compounds, to decrease variability in dispensing the formulation, to decrease physical separation of components of suspension or emulsion of the formulation and/or otherwise improve the ophthalmic formulation. Preferred viscosity agent for ophthalmic formulation includes cellulose derivatives, such as hydroxyethylcellulose.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the solution, emulsion or suspension formulation of Cochran by using the ophthalmic excipients taught by Cagel et al.
A person of ordinary skill in the art would have been motivated to make the solution, emulsion or suspension formulation of Cochran by using the ophthalmic excipients taught by Cagel et al. because those excipients are known to provide benefit to ophthalmic formulation. Further, the

optimization of a result effective parameter, e.g., effective concentration of an active ingredient, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

6. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbachyn et al. (US 5,688,792, IDS), in view of Cagle (WO 90/01933, IDS), and Fajardo et al.

7. Barbachynn et al. teaches the instant oxazolidinone, linezolid, is a known antibacterial agent, particularly for against gram-positive bacterial. Barbachyn et al. further teaches topical composition comprising the oxazolinone. See, particularly, the abstract, columns 6-7 and the claims.

8. Barbachyn et al. does not teach expressly a composition comprising an excipients that reduces a rate of removal of the composition from the eye.

However, Cagel teaches that, for a ophthalmic composition, viscosity increase above that of simple aqueous solutions may be desirable to increase ocular absorption of the active compounds, to decrease variability in dispensing the formulation, to decrease physical separation of components of suspension or emulsion of the formulation and/or otherwise improve the ophthalmic formulation. Preferred viscosity agent for ophthalmic formulation includes cellulose derivatives, such as hydroxyethylcellulose. Fajardo et al. teaches an oxazolidinone which is useful as an antibiotic ophthalmic agent. Fajardo et al. also teaches that this drug is valuable for treating eye infections that have failed to response to other antibiotics. See, particularly, page 114, both columns, page 117, left column, and page 118, left column.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a topical composition comprising linezolid and the excipients taught by Cagel.

A person of ordinary skill in the art would have been motivated to make a topical composition comprising linezolid and the excipients taught by Cagel. Further, one of ordinary skill in the art would have been motivated to make the topical composition suitable of ophthalmic use because oxazolidinone are know to be useful for treating eye infection. Further, the optimization of a result effective parameter, e.g., effective concentration of an active ingredient, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Response to Applicants' Remarks

Applicants amendments and remarks submitted February 17, 2004 have been fully considered. The newly added claims are not allowable for reasons set forth above.

With respect to the remarks of interferences, note since the claims are not allowable, the issue of interference is moot. See MPEP 2301.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

May 7, 2004